IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Lin Wang		Atty. Docket No.:	006401.00418
Serial No.:	10/687,498	Group Art Unit:	1732
Filed:	March 25, 2004	Examiner:	Monica A. Huson
For:	Process Using Cold-Water Soluble Extruded Starch	Confirmation No.:	9050

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Applicant respectfully requests review of the final rejection in the above-identified application.

I. ARGUMENT

A. Introduction and Background

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 4,076,846 to Nakatsuka *et al.* ("Nakatsuka") and U.S. Patent No. 5,849,233 to Altieri ("Altieri"). Claim 7 also stands rejected under § 103(a) as being obvious in view of Nakatsuka and Altieri as well as U.S. Patent No. 5,455,342 to Redding, Jr. ("Redding, Jr.").

Independent claim 1 recites:

> A process for preparing a film, comprising:
>
> providing a solution of an extruded starch product, said starch product having been prepared by a process comprising:
>
> providing a hydroxyalkyl starch, said starch being derivatized with a hydroxyalkyl substituent having from 2 to 6 carbon atoms; and
>
> extruding said starch in an extruder, said extruder having a barrel, a die, and at least one rotating shaft, said barrel having at least first and second zones, said first zone being upstream from said second zone, the temperature in said first zone being insufficient to gelatinize said starch and the temperature in said second zone being sufficient to gelatinize said starch, said starch being extruded in the presence of total moisture in said barrel no greater than about 25% by weight of said starch, said process including the step of controlling the rotational speed of said shaft to impart a specific

mechanical energy to said starch sufficient to result in a soluble extruded starch product that is capable of extrusion through said die at said rotational speed;

said solution having been prepared by mixing said starch product with water; and

forming a film from said solution.

The Examiner has committed a number of errors:

- Several claim elements are not found in any of the cited references. Specifically, the references fail to teach or suggest "a solution of an extruded starch product" or "forming a film." Nor do the references teach or suggest "an extruder having a barrel... said barrel having at least first and second zones" where the temperature in the first zone is insufficient to gelatinize the starch but the temperature in the second zone is sufficient.

- The cited references teach away from one another and from the claimed invention.

- The cited references teach away from the claimed hydroxypropyl starch.

B. The references cited by Examiner do not teach or suggest several claim limitations.

1. None of the cited references discloses a starch product.

Throughout the Final Office Action, the Examiner consistently and repeatedly confuses the ***starting materials*** disclosed by Nakatsuka with the products formed by extrusion. This error permeates the Examiner's reasoning and is of particular relevance to the claimed "extruded starch product."

The extruded starch product is said to be taught by Nakatsuka. The Altieri and Redding, Jr. references are secondary, and are relied on for other aspects of the claimed invention. But Nakatsuka simply does not disclose an extruded starch product. Nakatsuka purports to disclose a molding process that employs -- as ***a starting material*** -- a starch, in combination with a protein material. Nakatsuka describes a blend of the starting materials as a "molding composition." This molding composition is treated to produce molded or shaped articles.

Nakatsuka's product is not an "extruded starch product." In Nakatsuka's words, the complex formed upon extrusion of starch with protein "is not a simple mixture," but rather "it seems that some degree of union has been established between both materials by chemical reaction, thus contributing to

the improvement in physical properties." Column 6, lines 33-40. Whatever this product is, it is not a starch product. It is irrelevant that Nakatsuka teaches starch as a starting material.

The Examiner responded to this argument by pointing to Column 11, lines 1-6 in Nakatsuka. Here, Nakatsuka states that the article thus formed is a "starch-protein binary blend." This teaching confirms that the Examiner is wrong – i.e., that "some degree of union has been established between [starch and protein] by chemical reaction." Nakatsuka's disclosure of a starch-protein complex is insufficient to meet the claims.

2. None of the cited references disclose or suggest the claimed extrusion conditions

The claimed extrusion conditions are nowhere to be found in the cited references. The Examiner erroneously purports to find these conditions in Nakatsuka:

> Nakatsuka clearly discloses an extruder barrel having at least two zones at Column 13, lines 34-37. As previously noted, gelatinization occurs at about 150C-175C, so it is being interpreted that the cooler first zone would be insufficient to gelatinize the molding material, while the subsequent second/third zone would be sufficient for gelatinization. Note it is being interpreted that since Nakatsuka does disclose that gelatinization is effected via his process (Column 6, lines 14-19), 100% gelatinization occurs while or after the molding composition material is in the second/third zone."

This is completely wrong. In the passage relied on by the Examiner, Nakatsuka refers to gelatinization of starch ***in the starting materials,*** not upon extrusion.

The material prepared after extrusion by Nakatsuka is described as a starch-protein complex or "binary blend," and it is unclear whether any carbohydrate structure exists. It is further unclear whether the concept of a gelatinization temperature is at all applicable or relevant to this material. If the material is capable of gelatinization, it is unknown whether the conditions specified by Nakatsuka would meet the claimed requirements. Nakatsuka does disclose that starch was gelatinized before extrusion, so the concept of a first barrel zone at a temperature insufficient to gelatinize would be inapplicable. Simply put, the Examiner has again erred in relying on the starting material of Nakatsuka. Nakatsuka does not disclose or suggest the claimed extrusion conditions.

3. None of the cited references teach "forming a film from said solution."

The claims are drawn towards a process for preparing a film, including ***forming a film*** from a solution of the extruded starch product. Nakatsuka is completely silent as to forming a film. The sole place in Nakatsuka where film forming is said to be disclosed is the Abstract, but the Abstract does not

disclose the formation of a film. Nor are the other references relevant. The Examiner is simply wrong in finding these teachings in the cited art.

B. Redding, Jr. teaches away from Nakatsuka.

The Nakatsuka and Redding, Jr. references are incompatible. Redding, Jr. emphasizes the undesirability of chemically modifying starch, (*see* Column 2, line 30 *et seq.*), and teaches that one of the objects of the invention is "to provide a cost effective and energy efficient method of physical modification of starch and other substrates *without the necessity of chemical additives*," (Column 3, lines 46-49; emphasis added). (Column 2, lines 3-16).

Nakatsuka, on the other hand, teaches a modified "mixture of a starch material and a neutral inorganic salt of a protein . . . [wherein] some degree of union has been established between both materials," (Column 6, lines 34-40), and further teaches that the crosslinking between the starch material and the protein salt may be accelerated through ultraviolet irradiation, (Column 10, lines 10-17). Nakatsuka is therefore completely antithetical to Redding, Jr. -- one reference teaches to modify the starch heavily, the other teaches that chemical modifications to starch are not desirable and should be avoided.

In response to the argument, the Examiner points to Column 2 of Nakatsuka, in which Nakatsuka teaches that the starch starting material should not be modified. Again, the Examiner is confused between the starting material of Nakatsuka and the final product of Nakatsuka. The whole point of Nakatsuka is to modify the starch starting material very heavily with a protein. This teaching is not compatible with that of Redding, Jr.

C. Nakatsuka and Redding each teach away from hydroxyalkyl starches.

As the Examiner herself notes, Nakatsuka teaches away from starting with a starch starting material that has been modified. Nakatsuka therefore teaches away from the hydroyalkyl starch specified in the claims.

Redding, Jr. also teaches away from starch modification and specifically from hydroxyalkyl starches. The reference reports that prior art starches include substituted starches, and that known substituents include "acetate, succinate, phosphate, hydroxypropyl, and octenylsuccinate." According to Redding, Jr., "[e]ach of the above modification processes, however, suffer from various shortcomings and result in starch products with physical property limitations."

Only in hindsight would someone ignore these contrary teachings and employ a hydroxyalkyl starch.

II. CONCLUSION

The rejections are manifestly improper. Applicants wish to avoid appeal, and ask that this case be allowed.

Respectfully submitted,

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